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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 12 2010

OFFICE OF THE
CHIEF FINANCIAL OFFICER

The Honorable Dianne Feinstein
Chairman, Subcommittee on Interior,
Environment, and Related Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Madam Chairman:

Enclosed for your review is the Environmental Protection Agency's (EPA) Report to Congress on "Known Health Effects, Baseline Risk Assessment Approach, and On-Going Cleanup Activities at the Libby Asbestos Superfund Site, Libby, Montana" as required in Senate Report 111-38 of the FY 2010 Department of Interior, Environment and Related Agencies Appropriation Act (P.L. 111-88).

Senate Report 111-38 directs EPA to report within 180 days of enactment: (1) the currently known health risks (and includes a discussion of the anticipated associated long-term health care needs of the community); (2) the process used to determine a baseline risk assessment for adults and children in the community; and (3) cleanup activities that are planned while a Record of Decision is being developed.

Thank you for your support. Should you need additional information or have further questions, please contact me, or your staff may contact Ed Walsh at (202) 564-4594.

Sincerely,

Barbara J. Bennett
Chief Financial Officer

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 1 2 2010

OFFICE OF THE
CHIEF FINANCIAL OFFICER

The Honorable Lamar Alexander
Ranking Member, Subcommittee on Interior,
Environment, and Related Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Senator Alexander:

Enclosed for your review is the Environmental Protection Agency's (EPA) Report to Congress on "Known Health Effects, Baseline Risk Assessment Approach, and On-Going Cleanup Activities at the Libby Asbestos Superfund Site, Libby, Montana" as required in Senate Report 111-38 of the FY 2010 Department of Interior, Environment and Related Agencies Appropriation Act (P.L. 111-88).

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Sincerely,

BJBennett

Barbara J. Bennett
Chief Financial Officer

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 12 2010

OFFICE OF THE
CHIEF FINANCIAL OFFICER

The Honorable Jim Moran
Chairman, Subcommittee on Interior,
Environment, and Related Agencies
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed for your review is the Environmental Protection Agency's (EPA) Report to Congress on "Known Health Effects, Baseline Risk Assessment Approach, and On-Going Cleanup Activities at the Libby Asbestos Superfund Site, Libby, Montana" as required in Senate Report 111-38 of the FY 2010 Department of Interior, Environment and Related Agencies Appropriation Act (P.L. 111-88).

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Sincerely,

Barbara J. Bennett
Chief Financial Officer

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 1 2 2010

OFFICE OF THE
CHIEF FINANCIAL OFFICER

The Honorable Michael K. Simpson
Ranking Member, Subcommittee on Interior,
Environment, and Related Agencies
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Congressman Simpson:

Enclosed for your review is the Environmental Protection Agency's (EPA) Report to Congress on "Known Health Effects, Baseline Risk Assessment Approach, and On-Going Cleanup Activities at the Libby Asbestos Superfund Site, Libby, Montana" as required in Senate Report 111-38 of the FY 2010 Department of Interior, Environment and Related Agencies Appropriation Act (P.L. 111-88).

Senate Report 111-38 directs EPA to report within 180 days of enactment: (1) the currently known health risks (and includes a discussion of the anticipated associated long-term health care needs of the community); (2) the process used to determine a baseline risk assessment for adults and children in the community; and (3) cleanup activities that are planned while a Record of Decision is being developed.

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Sincerely,

Barbara J. Bennett
Chief Financial Officer

Enclosure

A Report to the Senate Appropriations Committee

Libby Asbestos Superfund Site
Libby, Montana

Known Health Risks
Baseline Risk Assessment Approach
On-going Cleanup Activities

Prepared by

U.S. EPA

Office of Solid Waste and Emergency Response
Office of Superfund Remediation and Technology Innovation

and

Region 08
Ecosystems Protection and Restoration

Coordinated With

Department of Health and Human Services
Agency for Toxic Substances and Disease Registry

and

U.S. EPA
Office of Research and Development

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A Report to the Senate Appropriations Committee

Known Health Risks, Baseline Risk Assessment Approach, and On-Going Cleanup Activities at the Libby Asbestos Superfund Site, Libby, Montana

Introduction

The Senate Appropriation Committee's Congressional reporting requirements from the Fiscal Year 2010 Department of Interior, Environmental and Related Agencies Appropriation Act (Senate Report 111-38, p. 56) include the following direction to the U.S. Environmental Protection Agency regarding the Libby Asbestos Superfund Site, Libby, Montana:

> "The Committee believes that as part of the recently declared public health emergency in Libby, Montana the Agency must develop a clear process for identifying long-term health care risks caused by a Superfund site contamination. The Committee is concerned that cleanup efforts to date have not adequately removed visible vermiculite and known public health risks. The Committee also recognizes that full community involvement is a critical component for long-term cleanup activities. To address these concerns, the Agency is directed to coordinate with the Department of Health and Human Services to identify the asbestos exposure risks associated with cleanup activities in Libby and their impact on long-term health care needs for the community.
>
> The Agency shall provide a report to the Committee within 180 days of enactment that details: (1) currently known health risks; (2) the process used to determine a baseline risk assessment for adults and children in the community; and (3) cleanup activities that are planned while a Record of Decision is being developed."

This report details as requested: (1) the currently known health risks (and includes a discussion of the anticipated associated long-term health care needs of the community); (2) the process used to determine a baseline risk assessment for adults and children in the community; and (3) cleanup activities that are planned while a Record of Decision is being developed.

Background

The Libby Asbestos Superfund Site, Libby, Montana is located in the northwest corner of Montana, 35 miles east of Idaho and 65 miles south of Canada. The towns of Libby and

Troy lie in a mountainous valley carved by the Kootenai River and are surrounded by the Cabinet Mountains. The site contains the former Zonolite Mountain vermiculite mine operated most recently by the W.R. Grace Company. The mine closed in 1990. At one time, the mine produced over 80% of the world's supply of vermiculite. The ore and resulting vermiculite products contained a mixture of hazardous amphibole asbestiform fibers. The mixture, known as Libby Amphibole asbestos, contains six different mineral types.

The U.S. Environmental Protection Agency (EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR), a division of the Department of Health and Human Services (DHHS) began collecting information in late November 1999 to assess the exposure and risk to public health from the asbestos-contaminated vermiculite in Libby. Removal actions to reduce exposure to Libby Amphibole began in 2000 and have continued to present. ATSDR conducted a community-wide health survey from 2000 to 2002. As a result of the ATSDR survey and EPA's investigations, Libby was added to EPA's National Priorities List (NPL) in October 2002.

Since that time, EPA has continued working closely with the community to reduce current and future exposure to Libby Amphibole. EPA established a program to inspect all properties in Libby to identify all properties impacted by asbestos contamination. Approximately 3500 properties were inspected in 2002 and 2003. EPA has and continues to conduct removal actions to reduce exposure to the Libby Amphibole asbestos. EPA is able to complete removal actions at approximately 150 properties during a construction season, which is limited in duration due to climate. As of January 2010, removal actions have been completed for former processing facilities, school yards, waste piles, and over 1200 residential and commercial properties. EPA estimates approximately 1,600 additional residential and business properties still need to be cleaned up. Removal actions for contaminated soil have focused upon addressing visible vermiculite or Libby Amphibole asbestos greater than 1%. These reductions in exposure are expected to reduce the incidence of asbestos-related disease in the community over the long term. However, due to the long latency period between exposure and expression of asbestos-related disease, new cases of asbestos-related disease attributable to historic exposures will likely continue to occur for several decades.

On June 17, 2009, EPA issued a Public Health Emergency (PHE) finding at the Libby Asbestos Superfund site in northwest Montana. The finding recognizes the continued significant threat to public health from actual and potential releases of asbestos contamination at the site. In recognition of this finding, EPA is working with DHHS and ATSDR, as they provide needed asbestos-related medical care to Libby and Troy residents. In addition, DHHS and ATSDR are examining the prevalence of health effects and the types of health effects associated to the Libby Amphibole.

The total number of residential and business properties to be cleaned up will depend upon the cleanup levels selected by EPA in its Records of Decision (ROD) for the site. EPA intends to issue a total of eight RODs for eight operable units (OUs) at the site, two of which will address the residential areas (in Libby and Troy); the remainder will address various processing areas and transportation corridors. The following is EPA's anticipated schedule for ROD completions: OU 1 and OU 2 (FY 2010); OU 5 (FY 2011); OU 4 and OU 7 (FY 2012); OU 6 and OU 8 (FY 2013); and OU 3 (FY 2014).[1] The cleanup levels for residential areas will depend on the toxicity values for Libby Amphibole, which EPA is developing from available human epidemiological studies of Libby Amphibole (based on quantitative health and exposure data from mine and mill workers) to support the risk assessments for the Site. These toxicity values are anticipated to be peer-reviewed and available by 2012 for use in developing risk assessments for the residential areas. EPA may issue remedy decisions for some processing areas of the site prior to completion of the Libby Amphibole-specific toxicity values, as these remedies are designed to prevent public exposure to any Libby Amphibole remaining in these areas and will expedite the reuse and revitalization of these lands by Libby for commercial purposes. The cleanup decisions will be re-assessed at a minimum of every five years as the Libby Amphibole animal toxicity studies and the long-term epidemiological studies are completed to ensure that any remedy decisions previously made continue to protect human health and limit exposure.

Currently Known Health Risks

This section describes the known health effects that have been reported for individuals exposed to Libby Amphibole asbestos and the potential associated long-term health care needs of the community. EPA's process for evaluating health risks from exposure to Libby Amphibole is described in a subsequent section.

The adverse effects of asbestos exposure to humans have been the subject of numerous investigations and publications (IARC 1977; WHO 2000; ATSDR 2000, 2001, 2003, 2004). Amphibole mineral fibers, including Libby Amphibole, are known to cause a variety of adverse health effects in exposed populations. The adverse health effects are generally classified as non-cancer effects and cancer. Because the latency of disease development ranges from ten to forty years, some adverse health effects may not yet be manifested in the Libby population (Rohs et al. 2008).

Non-Cancer Effects

Non-cancer effects resulting from asbestos exposure may include asbestosis, pleural abnormalities, and cardiovascular and autoimmune disease.

Asbestosis is a chronic disease characterized by the gradual formation of scar tissue in the spongy soft tissue of the lung. Build-up of scar tissue in the lung results in a loss of normal elasticity in the lung, which can lead to the progressive loss of lung function. The initial symptoms of asbestosis are shortness of breath, particularly during exertion.

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[1] OUs 1, 2 and 5 cover former processing areas; OUs 4 and 7 cover residential and commercial areas in Libby and Troy; OU6 covers BNSF railroad areas; OU8 covers the State highways' areas; and OU3 covers the mine property.

People with fully developed asbestosis tend to have increased difficulty breathing that is often accompanied by coughing. In severe cases, impaired respiratory function can lead to death. Asbestosis generally takes a long time to develop with a latency period from 10 to 20 years. Thus the disease may continue to progress long after exposure has ceased (ATSDR 2001).

Exposure to asbestos may induce several types of abnormalities in the pleura (the membrane surrounding the lungs). *Pleural effusions* are areas where excess fluid accumulates in the pleural space. Most pleural effusions last several months, although they may be recurrent. *Pleural plaques* are characterized by abnormal protein deposits in the lung, often with calcification. Pleural plaques are the most common manifestations of asbestos exposure (ATSDR 2001; American Thoracic Society 2004). *Diffuse pleural thickening* is characterized by fibrous thickening of the pleura, which may be extensive – covering a whole lobe or even an entire lung. The latency period for pleural abnormalities is usually about 10 to 40 years (American Thoracic Society 2004), although pleural effusions may occasionally develop as early as one year after first exposure (Epler and Gaensler 1982).

Some epidemiological studies provide evidence that chronic exposure to asbestos may increase the risk of several other types of non-cancer effects including cardiovascular effects (e.g., heart failure), retroperitoneal fibrosis (a fibrous mass in the back of the abdomen that blocks the flow of urine from the kidneys to the bladder), depressed cell-mediated immunity (ATSDR 2001), and autoimmune disease (Pfau et al. 2005; Noonan et al. 2006).

The prevalence of asbestos-related diseases in Libby is striking. A number of Libby Amphibole-specific studies (Armstrong et al. 1988; McDonald et al. 1986b; Amandus et al. 1987a,b; and Rohs et al. 2008) have observed increased incidence of pleural abnormalities in workers exposed to Libby Amphibole, including pleural calcification, pleural thickening and profusion of small opacities. Amandus and Wheeler (1987), McDonald et al. (1986a, 2004), and Sullivan (2007) reported that workers exposed to Libby Amphibole while working at the vermiculite mine and mill at Libby were more likely to die of non-malignant respiratory disease (NMRD) (i.e., asbestosis, chronic obstructive pulmonary disease, pneumonia, tuberculosis and emphysema) compared to the general U.S. population (white males). Studies by Peipins et al. (2003), Muravov et al. (2005), and Whitehouse (2004) also observed increased incidence of pleural abnormalities in workers and, in addition, in household contacts of former employees of the Libby mine and residents of Libby environmentally exposed to Libby Amphibole. ATSDR has also conducted studies of residents of Libby, screening a total of 7,307 participants including both former workers and non-workers. ATSDR found that the incidence rate of asbestosis in Libby was at least 40 times that of Montana and 60 times the national rate (based on 12 cases in ex-workers and one case in a household contact of a worker) (ATSDR 2000, 2003).

Cancer Effects

Many epidemiological studies have reported increased mortality from cancer in asbestos workers, especially from lung cancer and mesothelioma (ATSDR 2001). Based on these findings, and supported by extensive carcinogenicity data from animal studies, EPA has classified asbestos as a known human carcinogen (EPA 1993). Other cancers that have been suggested to be attributed to asbestos exposure in workers include renal cancer, ovarian cancer, and gastrointestinal cancer.

Exposure to asbestos is associated with increased risk of developing all major types of lung cancer (ATSDR 2001, 2004). The latency period for lung cancer generally ranges from about 10 to 40 years (ATSDR 2001). Early stages are generally asymptomatic, but as the disease develops, patients may experience coughing, shortness of breath, fatigue, and chest pain. Most lung cancer cases result in death. The risk of developing lung cancer from asbestos exposure generally is substantially higher in smokers than in non-smokers (Selikoff et al. 1968; Doll and Peto 1985; ATSDR 2001; NTP 2005).

Exposure to asbestos is associated with increased risk of developing mesothelioma (ATSDR 2001). Mesothelioma is a tumor of the thin membrane that covers and protects the internal organs of the body including the lungs and chest cavity (pleura), and the abdominal cavity (peritoneum). The latency period for mesothelioma is typically around 20-40 years (Lanphear and Buncher 1992; ATSDR 2001; Coffin et al. 1992; Mossman et al. 1996; Weill et al. 2004). By the time symptoms appear, the disease is most often rapidly fatal (British Thoracic Society 2001). Although there is a greater increase in lung cancer from asbestos exposure in smokers, mesothelioma risk generally does not appear to be increased by smoking (ATSDR 2002).

Excess deaths from kidney cancer among persons with known exposure to asbestos have been reported by a number of researchers (e.g., Selikoff et al. 1979; Enterline et al. 1987; and Puntoni et al. 1979). Smith et al. (1989) reviewed these studies and concluded that asbestos should be regarded as a probable cause of human kidney cancer. The IARC recently added ovarian cancer to disease associated with asbestos exposure (IARC, 2008).

A number of studies suggest, although not conclusively, that asbestos exposure may increase risk of cancer at various gastrointestinal sites (EPA 1986). NAS (2006) reviewed evidence regarding the role of asbestos in gastrointestinal cancers primarily following occupational exposures (these are assumed to be primarily by the inhalation route) and concluded the data are "suggestive but insufficient" to establish that asbestos exposure causes stomach or colorectal cancer. WHO (1996) concluded there are not adequate data to support the hypothesis that an increased cancer risk is associated with the ingestion of asbestos in drinking water. NAS (2006) also reviewed available data on the relationship between asbestos exposure and laryngeal and pharyngeal cancers, concluding that the data were "sufficient to infer a causal relationship between asbestos and laryngeal cancer and "suggestive but not sufficient to infer a causal relationship between asbestos exposure and pharyngeal cancer."

Several epidemiology studies have reported increased cancer mortality among workers exposed to the Libby Amphibole through mining and milling of contaminated vermiculite (McDonald et al. 1986, 2004; Amandus and Wheeler, 1987; Amandus et al. 1987a,b; Sullivan 2007). Compared to national mortality rates, statistically significant increased risks were seen for total cancer mortality, lung cancer mortality, and mesothelioma. The workers had 40% higher risk of mortality from all cancers, 70% higher risk of lung cancer mortality, and a 15-fold (1500%) increased risk of mortality from mesothelioma. Using the broader category of pleural cancer, the increased risk was even greater (23-fold (2300%)).

ATSDR has also studied cancer mortality statistics for Libby and surrounding areas. These studies generated data based on the entire population, regardless of occupational history or potential for exposures to asbestos. ATSDR found lung cancer mortality was 1.2 to 1.3 times higher than expected in Libby when compared to Montana and the United States. ATSDR found only 4 deaths specifically due to mesothelioma from a standard search of mortality records between the years 1979 to 1998 (ATSDR 2000). Because statistics on this extremely rare cancer are not routinely collected, it was difficult to quantify an increased risk for mesothelioma.

Potential Long-Term Health Care Requirements of the Community

The long-term health care requirements due to asbestos-related illnesses can be estimated, even though uncertainties exist. The requirements depend upon the illnesses caused by asbestos, occurrence of cases of each disease, and the medical costs for treatment over a lifetime.

Epidemiological data have been collected by ATSDR from 2000 to 2001 and from 2003 to 2007. These data reflect the occurrence of asbestos-related exposure and disease among approximately 7,000 screening participants. The pooled prevalence among workers, household contacts of workers and other residents ranges from 1.4% to 6.4% for asbestosis and 14.8% to 38.0% for pleural abnormalities. ATSDR's Division of Health Studies estimated that approximately 4,000 of 12,000 people living in the area may currently have clear indication of asbestos-related respiratory findings, such as asbestosis and pleural abnormalities.

One major uncertainty in predicting long-term requirements is accurately estimating the future occurrence of asbestos-related disease. The time period from asbestos exposure until disease is variable. This latency period depends on the natural history of the disease, age at exposure, and the timing and degree of exposure. New cases of asbestos-related disease will likely occur for several decades, extending the legacy of asbestos exposure in Libby. Efforts (described in subsequent sections) are underway to predict the future burden of asbestos-related illness in this population.

EPA, DHHS and ATSDR will continue to coordinate our efforts to assist the residents in Libby and Troy. EPA continues to work with the community to focus on the overall long term approach for investigation and remediation of the Libby Superfund Site to reduce current and future exposure to Libby Amphibole. At the same time, DHHS and ATSDR will help provide needed asbestos-related medical care to Libby and Troy residents and examine the health effects of exposure to Libby Amphibole. The Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act of 2010) includes a provision for Medicare coverage for Libby residents who meet the eligibility criteria.

Process to Determine a Baseline Risk Assessment for Adults and Children in the Community

EPA follows a step by step process to determine and implement a cleanup at a site listed on the NPL. The blueprint for this process is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), a regulation applicable to all federal agencies involved in responding to hazardous substance releases. The primary steps of the Superfund process include:

- *Removal Action* – conducted when immediate actions are needed to control or prevent the release of hazardous materials that would cause an immediate health concern;
- *Remedial Investigation* – includes studies that determine the nature and extent of contamination at the site and the factors causing the migration of the contaminant;
- *Human Health Risk Assessment* – characterizes the potential adverse health effects of human exposure to contaminants found at the site and examines the risks as they are presently observed and that may develop in the future should the contamination remain;
- *Feasibility Study* – describes options for cleanup using the results of the risk assessment along with engineering data and other considerations such as economic and legal concerns;
- *Proposed Plan* – summarizes the results of the Remedial Investigation, Human Health Risk Assessment, and Feasibility Study for the public and requests public comment on EPA's preferred cleanup alterative;
- *Record of Decision* – describes the remedy selected by EPA following public comment to reduce risks posed at the site to protective levels; and
- *Remedial Design/Remedial Action* – includes preparing for and implementing the remedy selected in the ROD.

EPA provides general guidance for conducting and reporting the results of risk assessments (EPA 1989) and additional guidance specific for asbestos contaminated Superfund sites (EPA 2008). The EPA 2008 guidance recommends assessment of exposure from inhalation of asbestos fibers using activity-based sampling (ABS), which simulates normal site-related activity. For example, ABS can be used to simulate a child's exposure scenarios (playing soccer, swinging, digging in soil, and running) in schools and special use areas that children frequent. The risk assessment process consists of four major steps: 1) data collection and evaluation; 2) exposure assessment; 3) toxicity assessment; and 4) risk characterization. A baseline risk assessment generally involves evaluation of the risk presented by a site under investigation to establish the basis for taking remedial action. A brief description of each of the steps follows.

Data Collection and Evaluation

The data collection and evaluation step includes: development of a sampling and analysis plan (with both a quality assurance project plan and field sampling plan); implementation of the sampling and analysis plan in a site investigation; analysis of the data; and selection of chemicals of concern (EPA 1989). For the Libby Asbestos Superfund Site, the chief chemical of concern is Libby Amphibole asbestos. Soil and air are the two major environmental media sampled at Libby. Air samples are collected on an air filter and the air filter is then analyzed by Transmission Electron Microscopy (TEM). Soil samples are collected using a 30-point compositing method, inspected for the presence of visible vermiculite (which is associated with the presence of Libby Amphibole) and analyzed by Polarized Light Microscopy (PLM).

Exposure Assessment

The exposure assessment evaluates how children and adults can contact environmental media and contaminants. An exposure pathway consists of a source of contaminant and release mechanism, a transport mechanism and medium, a point of human contact, and an exposure route. Only complete exposure pathways are relevant and, therefore, evaluated. The relevant exposure pathways are defined through the development of the Conceptual Site Model (CSM). The exposures are quantified by using the data collected (e.g., air concentrations obtained through activity based sampling) to calculate a time-weighted average exposure concentration. This process involves estimating daily intake, frequency of exposure, duration of exposure, and concentration of constituent in the media. Based on site-specific evaluation, the inhalation exposure pathway is the major route of human exposure in Libby. For Libby, the exposure concentration is calculated from the air concentrations measured by TEM and reported as Phase Contrast Microscope Equivalents (PCME) in structures per cubic centimeter of air (s/cc), a measure considered equivalent to the metric upon which the toxicity values are based.

Toxicity Assessment

The toxicity assessment evaluates and summarizes the toxicity data available for the chemicals of concern being evaluated in the risk assessment. There are two major classifications of toxicants: non-cancer toxicants and cancer-causing toxicants. Non-cancer toxicity factors (Reference Concentration (RfC)) for the inhalation route) are used to calculate a hazard index (a measure of non-cancer toxicity). Cancer toxicity factors (Inhalation Unit Risk factor (IUR) for the inhalation route) are used to estimate theoretical excess cancer risks which are probabilities. The source of toxicity values may originate with animal, human, or a combination of animal and human toxicity data. As yet, there are no Libby Amphibole-specific toxicity factors available, although EPA is sponsoring research to develop Libby Amphibole-specific toxicity factors for both cancer and non-cancer effects. The existing toxicity value for asbestos (i.e., IRIS Inhalation Unit Risk (IUR) for Asbestos (EPA 1986)), which includes studies of the health effects of chrysotile and amphibole (amosite and crocidolite) asbestos, has been applied in Libby to assess the potential cancer risks from exposure to Libby amphibole and to support interim cleanup decisions while the Libby Amphibole-specific toxicity values are being developed. The IRIS Asbestos IUR is based on human, occupational epidemiological investigations with an endpoint of mortality and morbidity for the combination of lung cancer and mesothelioma. There are no currently available non-cancer toxicity values for any form of asbestos that can be used to assess the potential risks for developing non-cancer diseases in Libby.

Risk Characterization

The risk characterization utilizes information from the exposure and toxicity assessments to estimate risks to children and adults. Two types of risks are quantified: non-cancer effects and theoretical excess cancer risk. The Hazard Quotient is the term used to describe the non-cancer risk. For the inhalation route, it is calculated as the ratio of the exposure concentration to the RfC. When the ratio is less than 1, there is minimal concern that adverse health effects will be expressed. When the ratio is greater than 1, there is a concern that adverse health effects will be expressed. Children (due to smaller size, higher exposure rate, and lower body mass) usually are the most sensitive to non-cancer effects. As there is no reference concentration value for Libby Amphibole (or any other form of asbestos), a hazard quotient cannot currently be calculated for the Libby site. However, as described below, EPA is currently developing a Libby Amphibole-specific RfC.

The cancer risk generally is expressed as a theoretical excess risk (a probability) of developing cancer over a lifetime exposure. In the case of asbestos, EPA has provided specific guidance for estimating theoretical excess lifetime cancer risk in the Framework for Investigating Asbestos-Contaminated Superfund Sites (EPA 2008) and the Risk Assessment Guidance for Superfund (RAGs), Part F, Inhalation Pathway Analysis (EPA 2009). The cancer risk from exposure to inhaled toxicants generally is estimated by multiplying an exposure concentration and the IUR for the toxicant. Cumulative risk for an individual exposed to several environments or exposure scenarios (e.g., playing in the dirt, mowing a lawn, athletic activities, etc.) is estimated by summing the risks from individual activities. The IRIS IUR for asbestos (EPA 1986) has been used to estimate the potential cancer risks from exposure to Libby Amphibole to support response actions while the Libby Amphibole-specific toxicity values are being developed. The Libby

Amphibole IUR and RfC are anticipated to be peer-reviewed and available by 2012 for use in developing risk assessments for the residential areas.

The risk characterization portion of the risk assessment usually contains an uncertainty section that discusses the strengths and weaknesses of the risk assessment. Topics such as exposure assumptions, data gaps, data quality, fate and transport modeling, toxicity factors, and mode of action of contaminants can influence the risk evaluation. The uncertainty section evaluates these factors qualitatively and sometimes quantitatively.

Libby Action Plan Toxicity Studies

EPA is conducting a series of research studies (collectively known as the Libby Action Plan) to increase our understanding of the toxicity of Libby Amphibole asbestos. These studies include development of toxicity values for both cancer and noncancer health effects specific to the Libby amphibole asbestos. These values will be based on analysis of existing human occupational epidemiological investigations of the health effects resulting from exposure to Libby Amphibole. The reference concentration (RfC), which is being developed in collaboration with the University of Cincinnati, will include an analysis of health effects from amphibole asbestos exposures reported in the Marysville, Ohio O.M. Scott occupational cohort. The IUR, which is being developed in collaboration with NIOSH scientists, will be based on the observed cancer mortality in the worker cohort from Libby. Additional toxicity information will be developed through a series of laboratory toxicological investigations addressing various forms of toxicity manifested by Libby Amphibole and several long-term human epidemiological studies, including a study focused on persons exposed to Libby Amphibole as children. Also underway as part of the Libby Action Plan are a series of studies designed to improve sampling and analysis methods for Libby Amphibole. These investigations are being coordinated by scientists at EPA Region 8, EPA National Center for Environmental Assessment (NCEA), EPA National Health and Environmental Effects Research Laboratory (NHEERL), ATSDR, and the U.S. Geological Survey (USGS).

Cleanup Activities Planned While a Record of Decision Is Developed

In order to reduce exposure to Libby Amphibole, EPA has and will continue to take extensive removal actions (see Table 1). Beginning in 2000, these actions have used a combination of removal of asbestos containing materials and capping to reduce public exposure to Libby Amphibole asbestos. The primary focus has been to remove contaminated soils (demonstrating visible vermiculite or Libby Amphibole asbestos greater than 1%) and accessible contaminated insulation from buildings. Activities initially (in 2000 and 2001) focused on the former W.R. Grace processing facilities (Export Plant, Screening Plant) that were large, highly contaminated properties. Other areas addressed included public properties where large volumes of vermiculite mining wastes had been extensively used (e.g., the High School and Middle School tracks and the Plummer Elementary ice rink which were made of vermiculite mine tailings). Residential and commercial property cleanups began in 2002. As of January 2010, removal actions have been conducted at former processing facilities, school yards, waste piles, streams, and more than 1200 residential and commercial properties as summarized in Table 1. EPA plans to continue these interim actions as expeditiously as possible while developing cleanup decisions for the site.

Table 1: Summary of Cleanup Actions at the Libby Asbestos Superfund Site, MT

	Large Projects	*Properties*	*Soil (yds^3)*	*VAI* (yds^3)*	**Debris (yds^3)**
2000	Former Processing Facilities	0	150,000	0	35,000
2001	Former Processing Facilities and Schools	8	120,000	0	5,000
2002	Former Processing Facilities, Schools and Residential and Commercial Properties	18	75,000	300	1,000
2003	Former Processing Facilities and Residential and Commercial Properties	157	40,000 15,000	2,200	250
2004	Former Processing Facilities and Residential and Commercial Properties	170	30,000 16,000	2,300	125
2005	Residential and Commercial Properties	225	31,000	2,700	200
2006	Residential and Commercial Properties	216	26,000	3,100	175
2007	Residential and Commercial Properties	160	46,000	2,200	150
2008	Residential and Commercial Properties and Creeks	149	49,857	1,304	593

2009	Residential and Commercial Properties and Creeks	159	102,991	681	671
Total		1,262	701,848	14,785	43,164

*VAI: Vermiculite Attic Insulation, also referred to by its product name as Zonolite Attic Insulation (ZAI)

While conducting interim cleanup actions, EPA is periodically faced with unplanned and sometimes urgent situations that could cause a release of Libby Amphibole. For example, there have been three house fires at homes that contained vermiculite insulation. Also, when property owners plan renovations where Libby Amphibole could be encountered EPA works to delineate areas of the property with Libby Amphibole contamination prior to the renovation, and then conducts preventative removals as appropriate to reduce exposure to the property owner. To reduce unplanned exposures to Libby Amphibole, EPA began providing a full-time service to assist property owners, firemen, construction workers and others in controlling their exposure to Libby Amphibole. This service is advertised throughout the community as the Environmental Resource Specialist (ERS) program. The ERS program typically receives around 40 calls per month requesting assistance. These calls result in approximately five small-scale responses per month.

EPA's cleanup decisions will be re-assessed at a minimum every five years as the Libby Amphibole animal toxicity studies and the long-term epidemiological studies are completed. The Libby Amphibole animal toxicity studies are anticipated to be completed in 2015; the long-term epidemiological studies are intended to evaluate health effects over periods in the range of 10 to 40 years.

The overall long-term approach for investigation and remediation of the Libby Asbestos Superfund Site includes characterization of contamination and assessment of risks to develop cleanup decisions for specific areas of the site. These characterization and assessment activities will be conducted while continuing removal response actions. Based on the characterization and risk assessment information, EPA will propose cleanup decisions in Proposed Plans which are made available for public comment. EPA's final cleanup decisions will be documented in Records of Decision.

EPA intends to issue a total of eight Records of Decision for the site: OU 1 and OU 2 (FY 2010); OU 5 (FY 2011); OU 4 and OU 7 (FY 2012); OU 6 and OU 8 (FY 2013); and OU 3 (FY 2014).[2] Due to the complex nature of the various operable units, the completion of Records of Decision will be phased over several years. EPA may issue remedy decisions for some processing areas of the site prior to completion of the Libby

[2] OUs 1, 2 and 5 cover former processing areas; OUs 4 and 7 cover residential and commercial areas in Libby and Troy; OU6 covers BNSF railroad areas; OU8 covers the State highways' areas; and OU3 covers the mine property.

Amphibole-specific toxicity values, as these remedies are designed to prevent public exposure to any Libby Amphibole remaining in these areas and will expedite the reuse and revitalization of these lands by Libby for commercial purposes. The remedy decisions for the residential areas will depend on the toxicity values for Libby Amphibole currently being developed as described above. As new information on the toxicity of Libby Amphiboles becomes available, EPA will re-evaluate previous cleanup decisions to ensure that public health and the environment continue to be protected. These re-evaluations occur at a minimum in five-year cycles, documented as Five Year Reviews. However, these evaluations may occur earlier if it is determined that imminent action is required.

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